IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

BOSTON SCIENTIFIC SCIMED, INC. and BOSTON SCIENTIFIC CORPORATION, Plaintiffs, v. CORDIS CORPORATION and JOHNSON & JOHNSON, INC., Defendants.	)	Civ. No. 03-283-SLR
BOSTON SCIENTIFIC SCIMED, INC. and BOSTON SCIENTIFIC CORPORATION, Plaintiffs, v. CORDIS CORPORATION, GUIDANT CORPORATION, GUIDANT SALES CORPORATION, JOHNSON & JOHNSON, INC., and ADVANCED CARDIOVASCULAR SYSTEMS, INC., Defendants.	)	Civ. No. 03-1138-SLR

MEMORANDUM ORDER

At Wilmington this 14th day of October, 2005, having heard oral argument and having reviewed the papers submitted in connection with the parties' proposed claim construction;

IT IS ORDERED that the disputed claim language in Claims 33 and 40 of U.S. Patent No. 6,251,920 B1 ("the '920 patent"), as

identified by the above referenced parties, shall be construed consistent with the tenets of claim construction set forth by the United States Court of Appeals for the Federal Circuit in Phillips v. AWH Corp., 415 F.3d 1303 (Fed. Cir. 2005), as follows:

1. "A cytostatic dose of a therapeutic agent."

Consistent with the specification[1] and the prosecution history,[2] the court construes this phrase to mean "An amount of a therapeutic agent that inhibits or retards the growth and multiplication of cells without killing the cells."

2. "Wherein the cytostatic dose is effective to increase the level of TGF-beta so as to inhibit smooth muscle cell proliferation, inhibit lipid accumulation, plaque stability, or any combination thereof."

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[1]See '920 patent, col. 3, ll. 30-33 ("Preferably, the compound significantly reduces the rate of completion of the cell cycle and cell division, and preferably is administrated at cytostatic, as opposed to cytotoxic, doses"); see also '920 patent, col. 15, ll. 56-62 ("the methods and dosage forms of this aspect of the present invention are useful for inhibiting vascular smooth muscle cells in a mammalian host, employing a therapeutic agent that inhibits the activity of the cell ... but does not kill the cell").

[2]During the prosecution history leading to the '920 patent, applicants distinguished their invention from prior art references by noting that "in vitro exposure of SMCs to tamoxifen does not kill the cells (i.e., tamoxifen is not cytotoxic), but instead prolongs the cell cycle time of nearly all the proliferating cells (i.e., the tamoxifen is acting cytostatically)." (C.A. No. 03-283-SLR, D.I. 382, ex. 9 at 4)

Consistent with the claim language, the specification and the prosecution history, the court construes this phrase to mean "the cytostatic dose of the therapeutic agent produces an increase in the amount of active TGF-beta, either by activating the latent form of TGF-beta or by stimulating the production of TGF-beta. The increase in the amount of active TGF-beta caused by the cytostatic dose must inhibit smooth muscle cell proliferation, inhibit lipid accumulation, increase plaque stability or any combination thereof."

With respect to the construction "increase plaque stability", the court construes this claim limitation in light of the specification[3] and prosecution history.[4] While the Federal

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[3]See '920 patent, col. 2, ll. 55-59 (stating in the summary of the invention that "the effective amount inhibits smooth muscle cell proliferation, inhibits lipid accumulation, **increases plaque stability**, or any combination thereof")(emphasis added); see also '920 patent, col. 3, ll. 33-40 (noting that one of the effects of stimulating TGF-beta production is that it "stabilizes an arterial lesion associated with atherosclerosis, i.e., **increases plaque stability**, to prevent rupture or growth of the lesion")(emphasis added). Neither party has directed the court to a place in the specification or the claims where there is a reference to inhibiting plaque stability.

[4]In the course of prosecution of the patent application leading to the '920 patent, Application Ser. No. 09/082,643, the applicants introduced claim 77 (which would subsequently issue as claim 33 of the '920 patent) which did not contain the word "increase" (or a like term) modifying "plaque stability." (C.A. No. 03-283-SLR, D.I. 382, ex. 11 at BSX 388274) However, applicants referenced as support for claim 77 a section of the application identical to what later issued as col. 2, ll. 50-59 of the '920 patent. (C.A. No. 03-283-SLR, D.I. 382, ex. 11 at BSX 388277, BSX 388155) That section, cited in the preceding footnote, provides a reference to "increasing" plaque stability.

Circuit has held that district courts may correct obvious minor typographical and clerical errors in patents,[5] the court does not observe such an error here and does not reach its construction of "increase plaque stability" through such a corrective measure.

As for the construction "produces an increase in the amount of active TGF-beta", it is clear from the specification that the therapeutic agent must produce an increase in the amount of active TGF-beta since only the active form of TGF-beta has biological activity.[6]

The court premises the construction "either by activating the latent form of TGF-beta or by stimulating the production of TGF-beta" on the guidance provided by the specification.[7]

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[5]Novo Indus., L.P. v. Micro Molds Corp., 350 F.3d 1348, 1354, 1357 (Fed. Cir. 2003)(citing I.T.S. Rubber Co. v. Essex Rubber Co., 272 U.S. 429 (1926)); see also Lemelson v. Gen. Mills, Inc., 968 F.2d 1202, 1203 (Fed. Cir. 1992)(adding the word "toy" to the preamble of a claim because "the deletion of 'toy' appears . . . to have been an inadvertent error when the patent was printed rather than an amendment to the claim"); Advanced Medical Optics, Inc. v. Alcon, Inc., 361 F. Supp. 2d 370 (D. Del. 2005)(correcting an error in a patent claim which was determined to be typographical).

[6]'920 patent, col. 8, ll. 46-49 ("To be rendered active and, therefore, capable of inhibiting vascular smooth muscle cell proliferation, the polypeptide form of TGF-beta must be cleaved to yield active TGF-beta"); '920 patent, col. 11, ll. 22-30 ("Latent TGF-beta must be cleaved . . . in order to become capable of inhibiting the proliferation of vascular smooth muscle cells"); see also '920 patent, col. 10, ll. 29-30 ("Vascular smooth muscle cell proliferation is inhibited by an active form of TGF-beta").

[7]The specification offers a method for "the administration of an amount of the compound of formula (I) to a mammal, such as

3. "TGF-beta."

Consistent with the specification,[8] the court construes "TGF-beta" to mean "TGF-beta and its functional equivalents and analogs."

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a human, effective to activate or stimulate production of TGF-beta." '920 patent, col. 3, ll. 59-62. In the '920 patent, the therapeutic agent administered is consistently referred to as "a TGF-beta activator or production stimulator." '920 patent, col. 2, ll. 52-55; col. 5, ll. 65-66. The "TGF-beta activator" refers to conversion of the latent form of TGF-beta to the active form. '920 patent, col. 8, ll. 50-53. The "TGF-beta production stimulator" refers to the production of TGF-beta. '920 patent, col. 3, ll. 54-60.

[8] See '920 patent, col. 8, ll. 39-41 (defining TGF-beta to include "transforming growth factor-beta as well as functional equivalents, derivatives and analogs thereof").